Election/Restriction

The Examiner stated that allegedly, this application contains inventions or groups of inventions which are not so linked as to form a single general inventive concept. The Examiner required applicant to elect a single invention to which the claims must be restricted from the following:

Group I. Claim 1-46 drawn to chimeric proteins, vectors encoding the chimeric proteins, and a method of using the chimeric proteins, and

Group II. Claim 47, drawn to transgenic non-human mammals.

The Examiner stated that the inventions do not relate to a single general inventive concept because 37 C.F.R. §1.475(b) does not provide for multiple independent products. The Examiner stated that the transgenic non-human mammals of Group II is an independent product from the chimeric proteins and vectors encoding the chimeric proteins of Group I. The Examiner stated that since the products of Groups I and II are independent, a holding of lack of unity is proper.

The Examiner stated that this application contains claims directed to more than one species of the generic inventions. The Examiner stated that these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept. The Examiner stated that the species are as follows:

A. Chimeric proteins comprising:

(a) a zinc three-finger DNA binding polypeptide linked to a CpG-specific DNA methyltransferase polypeptide,

(b) a mutated Lex A binding polypeptide linked to a cytosine methyltransferase polypeptide, and

(c) at least a portion of a mutated *M. SssI* DNA methyltransferase protein or at least a portion of a mutated mammalian DNA methyltransferase protein.

The Examiner stated that the species do not relate to a single general inventive concept because the chimeric proteins comprise distinct amino acid sequences and are thus independent products, therefore, a holding of lack of unity is proper.

B. Target genes associated with:

(a) cancer,

(b) a central nervous system disorder,

(c) a blood disorder,

(d) a metabolic disorder,

(e) a cardiovascular disorder,

(f) an autoimmune disorder, and

(g) an inflammatory disorder.

The Examiner stated that the species do not relate to a single general inventive concept because they lack the same or corresponding special technical features for the following reasons: the claimed disorders have different etiologies, therefore, the target genes associated with each disorder are likely to be distinct, and would require targeting to different cell populations and different tissues. Thus, the Examiner stated that different technical considerations would be necessary for targeting diseases of different etiologies which affect different cell types.

C. Target genes wherein the target gene is:

(a) endogenous, or

(b) foreign.

The Examiner stated that the species do not relate to a single inventive concept because they lack the same or corresponding special technical features for the following reasons: the claim-designated endogenous and foreign target genes have distinct structures based on their origin, including the promoter regions to be targeted. Thus, the Examiner stated that determination of the ability to methylate an endogenous target gene and a foreign target gene (such as viral or retroviral target genes), and the methods for delivering the chimeric protein to chromosomal (as in the case of endogenous target genes) versus extra-chromosomal (which can be the case for viral genes) genetic material would require different technical considerations.

D. Multicellular organisms including:
   (a) plants, and
   (b) animals.

The Examiner stated that the species do not relate to a single general inventive concept because they lack the same or corresponding special technical features for the following reasons: the methods for inhibiting expression of a target gene in a multicellular organism such as an animal would require different technical considerations for delivery of the chimeric protein compared to methods for inhibiting expression of a target gene in a multicellular organism such as a plant in view of the anatomical and physiological distinctions between plants and animals.

The Examiner stated that the applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner stated that the reply must also identify

the claims readable on the elected species, including any claims subsequently added. The Examiner stated that an argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The Examiner stated that upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141. The Examiner stated that if claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP §809(a).

The Examiner stated that applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

In reply, applicant elects Group I directed to claims 1-46. Applicant elects the following species as required by the Examiner:

A. Chimeric proteins comprising (a) zinc-finger DNA binding polypeptide linked to a CpG-specific DNA methyltransferase polypeptide.

B. Target genes associated with: (a) cancer.

C. Target genes wherein the target gene is: (a) endogenous.

D. Multicellular organisms including: (b) animals.

Accordingly, applicant looks forward to receiving an action on the merits.

Sequence Compliance

The Examiner stated that this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. §1.82(a)(i) and (a)(ii). However, the Examiner stated that this application fails to comply with the requirements of 37 C.F.R. §1.81 through §1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant attaches hereto as Exhibit A a copy of the Notice to Comply.

In reply, applicant submits herewith a Sequence Listing attached hereto as **Exhibit B** in compliance with the requirements of 37 C.F.R. §1.824. In addition, applicant submits herewith a computer readable copy of the Sequence Listing on the enclosed computer diskette, which has the same content as the paper copy attached as **Exhibit B**. Applicant submits as **Exhibit C**, a Statement in accordance with 37 C.F.R. §1.821(f) certifying that the computer readable form containing the nucleic acid and/or amino acid sequences required by 37 C.F.R. §1.821(f) and submitted in connection with the above-identified application, has the same information which is submitted herewith as **Exhibit B** entitled "Sequence Listing". In addition, applicant has amended the specification to include references to SEQ ID NOS.

Thus, the application now complies with the requirements of 37 C.F.R. §1.824 and applicant requests that the Examiner withdraw this objection.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit

Account No. 03-3125.

Respectfully submitted,

Jane M. Love

John P. White
Registration No. 28,678
Jane M. Love
Registration No. 42,812
Attorneys for Applicant
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents Washington, D.C. 20231

Jane M. Love 4/4/00

John P. White Date
Reg. No. 28,678
Jane M. Love
Reg. No. 42,812